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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,007

10/19/2006

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

04/01/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/579,007	Applicant(s) PANICALI ET AL.	
	Examiner Anne Marie S. Wehbe	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-10, 12, 13, 16-22 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-10, 12, 13, 16-22 and 40 is/are rejected.
- 7) ☒ Claim(s) 4 and 17-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/30/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment and response received on 12/30/09 has been entered. Claims 6, 11, 14-15, 23-39, and 41-43 have been canceled. Claims 1-5, 7-10, 12-13, 16-22, and 40 are currently pending and under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

Information Disclosure Statement

The information disclosure statement (IDS) filed on 12/30/09 meets the requirements of 37 CFR 1.97 and 1.98 and has been considered by the examiner. An initialed and signed copy of the 1449 is attached to this action.

Claim Objections

The objection to claim 7 is withdrawn in view of the amendment to claim 7.

Claim 4 is newly objected to because of the following informalities: claim 4, as amended, recites "...contained within the first, second, or both vectors. vector". The extra "vector" after the period appears to be a typographical error. Appropriate correction is required.

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Claims 17-22 are newly objected to because of the following informalities: claim 17 depends on canceled claim 11. Claims 18-22 depend on claim 17 and thus also depend on a canceled claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The rejection of claims 35-38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of the cancellation of these claims.

Claims 17-22 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The present amendment canceled claim 11. However, claim 17 continues to depend on now canceled claim 11. Claims 18-22 further depend on claim 17 and thus also on a canceled claim. As such, the claims as written lack any specific method steps and further lack antecedent basis for “the first poxvirus vector” and “the second poxvirus vector”. Therefore, in their current form, further examination of claims 17-22 for compliance with the requirements of 35 U.S.C. 112, first paragraph, 35 USC 102, and 35 USC 103, is precluded.

It is suggested that applicant amend the dependency of claim 17 to a pending claim to overcome this rejection.

Claim Rejections - 35 USC § 102

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The rejection of claims 1-14, and 33-40 under 35 U.S.C. 102(b) as being anticipated by WO 00/34494 (2000), hereafter referred to as Schlom et al, is withdrawn in view of the cancellation of claims 6, 11, 14, and 33-39, and the amendment of claims 1-5, 7-10, 12-13 to recite that the method comprises the administration of a first poxvirus vector which encodes both MUC1 and CEA and thereafter the administration of a second poxvirus which also encodes both MUC1 and CEA. While Schlom et al. does teach to make and use a single poxvirus vector encoding more than one tumor associated antigen, and further teaches poxvirus vectors which encode MUC1 or CEA, Schlom et al. does not specifically teach to make or use a single poxvirus vector which encodes both MUC1 and CEA. As such, the 102 rejection has been withdrawn.

Claim Rejections - 35 USC § 103

Claims 1, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/34494 (2000), hereafter referred to as Schlom et al., in view of WO 01/24832 (2001), hereafter referred to as Pecher, is withdrawn over canceled claims 14-15, and maintained or newly applied to amended claims 1-5, 7-10, 12-13, 16, and 40. Applicant's amendments to the claims and arguments have been fully considered but have not been found persuasive in overcoming the rejection for reasons of record as discussed in detail below.

The claims as amended are now limited to the administration of a first poxvirus encoding both MUC1 and CEA followed by the administration of a second poxvirus vector encoding both MUC1 and CEA. This aspect of the invention was encompassed by previously pending claim 15 which was included in the rejection of record.

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It is noted that applicant has provided a combined argument against the two separate 103 rejections present in the previous office action. However, the instant rejection is based on the teachings of Schlom et al. in view of Pecher. Thus, arguments directed against Grosenbach are not relevant to the instant rejection.

The applicant argues that consideration of the *Graham* factors indicates that the pending claims are unobvious in the view of the cited references. Specifically, the applicant argues that neither Schlom et al. nor Pecher teach a single poxvirus vector encoding both MUC1 and CEA and that therefore the claims are nonobvious.

In response, the rejection of record clearly states that Schlom et al. teaches the administration of more than one dose of recombinant poxvirus encoding a tumor antigen, such as MUC1 or CEA, or a prime and boost delivery method where a first vector is administered followed by a administration of a second vector, where the first and second vectors are different strains of poxvirus (Schlom et al., in particular page 39). The rejection of record further states that Schlom et al. teaches that the poxvirus vector can encode more than one tumor associated antigen, and/or further encode a cytokine such as GM-CSF (Schlom et al., pages 5, 31-37). The only teaching missing from Schlom et al. is a specific teaching to choose MUC1 and CEA as the tumor associated antigens to express together in a recombinant poxvirus vector. Pecher was cited to supplement Schlom et al. by teaching the combined administration of vectors, including vaccinia virus vectors, encoding MUC1 and CEA to human patients for the treatment of tumors (Pecher et al. pages 4-6). Thus, Schlom et al. provides the teaching that the poxvirus can encode more than one tumor associated antigen, and Pecher provides the motivation to choose the combination of MUC1 and CEA to express in a single poxvirus vector as taught by Schlom et al.

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Therefore, it is reiterated that in view of the teachings of Schlom et al. to use poxvirus vectors encoding more than one target tumor associated antigen for the treatment of cancers including breast cancer, and the motivation provided by Pecher to co-administer vaccinia virus encoding MUC1 and CEA to treat human tumors, it would have been *prima facie* obvious to the skilled artisan at the time of filing to make and use a single poxvirus vector encoding MUC1, CEA, and TRICOM (B7, ICAM-1, and LFA-1) in the methods of treating cancer, such as breast cancer, taught by Schlom et al.. Further, based on the detailed guidance provided by Schlom et al. for making poxvirus vectors which encode multiple heterologous genes, and the successful demonstration by both Schlom et al. and Pecher that poxvirus encoding tumor antigens such as CEA and MUC1 can successfully prevent tumor growth, the skilled artisan at the time of filing would have had a reasonable expectation of success in treating breast cancer using the methods of Schlom et al. as modified by Pecher et al.

The applicant further argues that there are "unexpected benefits" to the present invention which would have been nonobvious at the time of filing. In particular, the applicant has submitted a post-filing reference, Gulley et al., which according to applicant shows a significant increase in antigen-specific MUC or CEA immune response in patients following a prime-boost protocol as claimed, and provides evidence of clinical benefit.

In response, the applicant is reminded that the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a

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long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. MPEP 716.01(c). MPEP 716.02(g) further states: "The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 USC 25 and 18 U.S.C. 1001." Permitting a publication to substitute for expert testimony would circumvent the guarantees built into the statute. *Ex parte Gray*, 10 USPQ2d 1922, 1928 (Bd. Pat. App. & Inter. 1989). Publications may, however, be evidence of the facts in issue and should be considered to the extent that they are probative. With this in mind, the post-filing publication cited in applicant's response has been considered. While Gulley et al. reports the practice of one embodiment of the method as claimed in human patients, there are no teachings in Gulley et al. that the co-expression of MUC1 and CEA resulted in "unexpected" or surprising results. In fact, while Gulley et al. on page 3060 suggests that vectors directed against multiple TAAs may evoke additive or synergistic immune responses, Gulley et al. does not report any additive or synergistic responses using the MUC1/CEA TRICOM vaccine. On the contrary, on page 3068, Gulley et al. remarks that a previous trial using a CEA TRICOM vaccine reported greater CEA specific T cell responses than those observed in the MUC1/CEA TRICOM trial. Therefore, Gulley et al. does not support applicant's argument for unexpected results.

Thus, for the reasons set forth above, the rejection of record stands.

The rejection of claims 1, 6-7, 11, and 17-22 under 35 U.S.C. 103(a) as being unpatentable over WO 00/34494 (2000), hereafter referred to as Schlom et al. in view of

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Grosenbach et al. (2001) Cancer Research, Vol. 61, 4497-4505, is withdrawn over canceled claims 6 and 11, withdrawn over amended claims 1 and 7 in view of the limitation of these claims the administration of first and second poxvirus vectors which each encode both MUC1 and CEA, and further withdrawn over claims 17-22 in view of the fact that these claims depend on a canceled claim and contain no method steps for consideration of obviousness under 35 U.S.C. 103, see the new rejection of claims 17-22 under 35 U.S.C. 112, second paragraph, above.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, the technology center fax number is (571) 273-8300. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/

Primary Examiner, A.U. 1633